510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:
K033070

B. Analyte:
Borrelia burgdorferi

C. Type of Test:
Enzyme-Linked Immunosorbent Assay

D. Applicant:
Trinity Biotech USA

E. Proprietary and Established Names:
Trinity Biotech Captia *Borrelia burgdorferi* IgM Enzyme-Linked Immunosorbent Assay (ELISA)

F. Regulatory Information:

1. Regulation section:
   866.3830
2. Classification:
   Class II
3. Product Code:
   LSR
4. Panel:
   83

G. Intended Use:

1. Intended use(s):
   The Trinity Biotech Captia *Borrelia burgdorferi* (*B. burgdorferi)* IgM Enzyme-Linked Immunosorbent Assay (ELISA) is intended for the qualitative presumptive (first-step) detection of IgM antibodies to *Borrelia burgdorferi* in human serum. This ELISA should only be used for patients with history, signs and symptoms that are consistent with Lyme disease. Equivocal or positive results must be supplemented by testing with a standardized Western Blot (second-step) procedure. Positive supplemental (second-step) results are supportive evidence of exposure to *B. burgdorferi* and can be used to support a clinical diagnosis of Lyme disease. The diagnosis of Lyme disease must be made based on history, signs (such as erythema migrans), symptoms, and other laboratory data, in addition to the presence of antibodies to *B. burgdorferi*. Negative results (either first- or second-step) should not be used to exclude Lyme disease.

2. Indication(s) for use:
   The *Borrelia burgdorferi* IgM ELISA kit is an Enzyme-Linked Immunosorbent Assay (ELISA) for the qualitative presumptive detection of IgM antibodies to *Borrelia burgdorferi* in human serum. This ELISA should only be used for patients with signs and symptoms that are consistent with Lyme disease. Equivocal or positive results must be supplemented by testing with a standardized Western blot procedure. Positive supplemental results are supportive evidence of exposure to *B. burgdorferi* and can be used to support a clinical diagnosis of Lyme disease.
3. Special condition for use statement(s):
   Not applicable
4. Special instrument Requirements:
   Single or dual wavelength microplate reader with 450 nm filter

H. Device Description:

This is an ELISA kit that contains purified *B. burgdorferi* (strain B-31, passed less then 15 times, washed, concentrated and detergent treated in glycine buffer) antigen coated microassay plate in a 96 well configuration containing alternating strips of inactivated antigen and control antigen, serum diluent, cutoff calibrator, a high positive, low positive, and negative control, horseradish-peroxidase conjugate, Chromogen/substrate solution, wash buffer and stop solution.

I. Substantial Equivalence Information:

1. Predicate device name(s):
   Borrelia Burgdorferi IgM ELISA Test System
2. Predicate K number(s):
   K965129
3. Comparison with predicate:

Similarities		
Item	**Device**	**Predicate**
Intended Use	Presumptive detection of B. burgdorferi IgM antibodies in human serum	Presumptive detection of B. burgdorferi IgM antibodies in human serum
Reagents	Tris BSA Serum Diluent Tris Tween Wash Buffer Goat anti-human IgG (Fc)	Tris BSA Serum Diluent Tris Tween Wash Buffer Goat anti-human IgG (Fc)
Technology	ELISA	ELISA
Reagents	Horseradish Peroxidase Conjugate TMB enzyme substrate Sulfuric Acid Stop	Horseradish Peroxidase Conjugate TMB enzyme substrate Sulfuric Acid Stop
Procedure	Serum incubation-20 min Conjugate incubation-20min Substrate incubation-10min	Serum incubation-20 min Conjugate incubation-20min Substrate incubation-10min

	Stop-add 100µl of stop solution Read at 450nm	Stop-add 100µl of stop solution Read at 450nm
Calculations	1 cutoff calibrator, high, low, and negative controls Multiply cutoff calibrator by correction factor	1 cutoff calibrator, high, low, and negative controls Multiply cutoff calibrator by correction factor
Differences		
Item	**Device**	**Predicate**
None	None	None

J. Standard/Guidance Document Referenced (if applicable):

Not applicable

K. Test Principle:

Enzyme-Linked Immunosorbent Assays (ELISA) rely on the ability of biological materials, (i.e., antigens) to adsorb to plastic surfaces such as polystyrene (solid phase). When antigens bound to the solid phase are brought into contact with a patient's serum, antigen specific antibody, if present, will bind to the antigen on the solid phase forming antigen-antibody complexes. Excess antibody is removed by washing. This is followed by the addition of goat anti-human IgG conjugated with horseradish peroxidase which then binds to the antibody-antigen complexes. The excess conjugate is removed by washing, followed by the addition of Chromogen/Substrate, Tetramethylbenzidine (TMB). If specific antibody to the antigen is present in the patient's serum, a blue color develops. When the enzymatic reaction is stopped with 1N H2SO4, the contents of the wells turn yellow. The color, which is indicative of the presence of antibody in the serum, can be read on a suitable spectrophotometer or ELISA microwell plate reader.

L. Performance Characteristics (if/when applicable):

1. Analytical performance:
    a. *Precision/Reproducibility:*
    Not Applicable. This is a change in distributor only. Performance characteristics were established in K965129.
    b. *Linearity/assay reportable range:*
    Not Applicable
    c. *Traceability (controls, calibrators, or method):*
    Not Applicable
    d. *Detection limit:*
    Not Applicable
    e. *Analytical specificity:*
    Not Applicable
    f. *Assay cut-off:*
    Not Applicable
2. Comparison studies:
    a. *Method comparison with predicate device:*

Not Applicable

b. Matrix comparison:
Not Applicable

3. Clinical studies:
   a. Clinical sensitivity:
   Not Applicable
   b. Clinical specificity:
   Not Applicable
   c. Other clinical supportive data (when a and b are not applicable):
   Not Applicable
4. Clinical cut-off:
   Not Applicable
5. Expected values/Reference range:
   Not Applicable

M. Conclusion:

The Trinity Biotech Captia *Borrelia burgdorferi* IgM ELISA is substantially equivalent in performance to the predicate for the presumptive detection of *B. burgdorferi* in human serum.